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| APPLICATION NO.   | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|------------------|----------------------|-------------------------|------------------|
| 10/799,681  | 03/15/2004       | Hirokazu Annoura     | 47259-0454              | 8653             |
| 55694 7590 05/01/2007<br>DRINKER BIDDLE & REATH (DC)<br>1500 K STREET, N.W. |                  |                      | EXAMINER  DESAI, RITA J |                  |
| SUITE 1100<br>WASHINGTO   | N, DC 20005-1209 | :                    | ART UNIT                | PAPER NUMBER     |
| ,   |                  |                      | 1625                    |                  |
|   |                  |                      | MAIL DATE               | DELIVERY MODE    |
|   |                  |                      | 05/01/2007              | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s)   |  |
|-----------------|----------------|--|
| 10/799,681      | ANNOURA ET AL. |  |
| Examiner        | Art Unit       |  |
| Rita J. Desai   | 1625           |  |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 10 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1, X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires <u>3</u> months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The Notice of Appeal was filed on . A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. Torpurposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: \_ Claim(s) withdrawn from consideration: \_\_\_\_\_. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER

- 11. 

  The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see addendum.
- 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. Other: \_\_\_\_\_.

Rita J. Desai **Primary Examiner** Art Unit: 1625

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Addendum to the Advisory

The arguments to overcome the double patenting rejections are not convincing.

The US 6455549 claims are clearly drawn to ca overload compounds with overlapping matter.

$$R - A - B - N$$

wherein, R is a hydrogen atom, an optionally substituted phenyl group, an optionally substituted phenoxy group, or an optionally substituted benzoyl group, A is a connecting bond, a cycloalkylene group, or an alkenylene group optionally substituted with a lower alkyl group, B is an alkylene group optionally substituted with a hydroxyl group or an alkoxy group or a group -NHCO(CH<sub>2</sub>),-, where n is an interger of 1 to 5, E is a connecting bond, an oxygen atom, or a methylene group, X is a hydroxyl group or a hydrogen atom, provided that, when E is an oxygen atom or a methylene group, X is not a hydrogen atom, and Y and Z may be the same or different from each other and represent a hydrogen atom, a halogen atom, an alkoxy group, or an akyl group optionally substituted with a halogen atom; and also provided that, when X is a hydroxyl group, and R is a hydrogen atom or an optionally substituted phenyl group, and A is a connecting bond or a cycloalkylene group, then B is not a group —NHCO(CH<sub>2</sub>)<sub>n</sub>—, where n is an integer of

US'549 claim 6 reads 1 to 5.

and applicants

instant claim is

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## 11. (Currently amended) A compound having the formula (I'):

wherein, R' is an optionally substituted phenyl group, an optionally substituted phenoxy group, or an optionally substituted benzoyl group, A is a connecting bond, B is an alkylene group optionally substituted with a hydroxyl group or an alkoxy group, E is an oxygen atom, X is a hydroxyl group, and Y and Z may be the same or different from each other and represent a hydrogen atom, a halogen atom, an alkoxy group, or an alkyl group optionally substituted with a halogen atom, provided that, when X is a hydroxyl group and R' is an optionally substituted phenyl group, B is not an unsubstituted alkylene group, and when R' is an optionally substituted phenoxy group, B is not an unsubstituted alkylene group, or its pharmaceutically acceptable salt.

Thus the claim can have R' as a phenoxy and B being a substituted alkylene.

The amendment does no preclude the compounds of US'549

US '549 also reads and has all the limitations to meet the claim.

Applicants arguments that the claims are drawn to group II, as applicants have not then amended the claims to delete that which was claimed before. Hence the rejection still stands.

The rejection of claims 11,12, 14-16 and 19 over claims 1-10 US 6, 838,470 also stands.

Applicants have also now mentioned 10/196,362 which is another divisional of

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09/043, 563 . applicants have not amended the claims to have a clear line of demarcation and hence the rejection still stands.

The '470 patent has claims that read on compounds with a similar scope.

Applicants arguments are not convincing. The claims have overlapping subject matter.

There is no need for reasoning of obvious modifications.

Q in the US '470 patent reads on all the variables of the instant application.

US Supreme Court, KSR v Teleflex April 30 2007.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design Granting patent protection to advances that trends. would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684.

The examiner can normally be reached on Monday - Friday, flex time..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai Primary Examiner Art Unit 1625 Neso107

R.D. April 30, 2007